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Employer Wellness Programs: Health Reform and the Genetic Information Nondiscrimination Act

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Summary

Health reform is a major issue on the domestic policy agenda of the 111th Congress. Congress has been considering a number of policy proposals to reform the health delivery system that aim to improve health care quality, reduce health care costs, and expand access to care. A range of proposals have targeted reform of the delivery system through an increased focus on prevention and wellness in an effort to encourage individuals to adopt healthier lifestyles. One prominent policy lever being considered in some health delivery reform proposals is employer wellness programs. Employer wellness programs often focus on improving wellness overall, but may target a specific disease (e.g., diabetes) or behavior (e.g., smoking), may include the provision of a range of health or other services, and are offered by employers to employees through the workplace or other setting.

Most if not all employer wellness programs collect medical information from participants. Programs may request or require participating employees to answer questions about family history of certain diseases, conditions, or disorders. This information falls under the definition of genetic information under the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110-233), and therefore its acquisition and use by employers is strictly protected and is protected differently than is acquisition of other medical information. Although GINA generally prohibits the acquisition of genetic information, it does allow for its collection as part of a wellness program, subject to certain requirements. As Congress considers the role that employer wellness programs may or can play in reforming the health care system, the potential interaction between GINA and any wellness program provisions is likely to be assessed.

This report provides an overview of GINA generally, a description of GINA's statutory exception allowing for the collection of genetic information pursuant to a wellness program, and a discussion of some of the key issues that either have arisen or may arise as lawmakers consider the role of these programs in health reform.

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Introduction

Health reform is a major issue on the domestic policy agenda of the 111th Congress. Congress has been considering a number of policy proposals to reform the health delivery system that aim to improve health care quality, reduce health care costs, and expand access to care. A range of proposals have targeted reform of the delivery system through an increased focus on prevention and wellness in an effort to encourage individuals to adopt healthier lifestyles. One prominent policy lever being considered in some health delivery reform proposals is employer wellness programs. Employer wellness programs often focus on improving wellness overall, but may target a specific disease (e.g., diabetes) or behavior (e.g., smoking), may include the provision of a range of health or other services, and are offered by employers to employees through the workplace or other setting. These programs may include the provision of incentives for participation, ranging from additional paid time off to reduced insurance premium contributions.

Most if not all employer wellness programs collect medical information from participants. Programs may request or require participating employees to answer questions about family history of certain diseases, conditions, or disorders. This information falls under the definition of genetic information under the Genetic Information Nondiscrimination Act of 2008 (GINA), and therefore its acquisition and use by employers is strictly protected and is protected differently than is employer acquisition of other medical information.[1] Although GINA generally prohibits the acquisition of genetic information, it does allow for its collection as part of a wellness program, subject to certain requirements.

As Congress considers the role that employer wellness programs may or can play in reforming the health care system, the potential interaction between GINA and any wellness program provisions is likely to be assessed. Congress may, of course, enact legislation that may in effect or directly amend the requirements of GINA. This report provides an overview of GINA generally, a description of GINA's statutory exception allowing for the collection of genetic information pursuant to a wellness program, and a discussion of some of the key issues that either have arisen or may arise as lawmakers consider the role of these programs in health reform.[2]

Overview of the Genetic Information Nondiscrimination Act of 2008 (GINA)

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21st century, was enacted. GINA, P.L. 110-233, prohibits discrimination by health insurers and employers based on genetic information. Genetic information is considered sensitive because it may be predictive and can affect not only an individual but also family members.[3]

GINA is divided into two main parts: Title I, which prohibits discrimination by health insurers based on genetic information, and Title II, which prohibits discrimination in employment based

[1] Title II of GINA defines genetic information as "with respect to any individual, information about such individual's genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual." P.L. 110-233, Section 201(4)(A).

[2] For a discussion of the legal issues relating to wellness programs, see CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones.

[3] For more information about GINA, please see CRS Report RL34584, *The Genetic Information Nondiscrimination Act of 2008 (GINA)*, by Nancy Lee Jones and Amanda K. Sarata.

on genetic information. Title I of GINA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as the Social Security Act, to prohibit health insurers from engaging in genetic discrimination and to strengthen and clarify existing HIPAA nondiscrimination and portability provisions. In this way, group plans under ERISA, group and individual plans under the PHSA, Church Plans under the IRC, and Medigap plans under the SSA are all brought under the jurisdiction of the law. The complexity of the health care financing system required this multifaceted approach in order to ensure protection for all individuals, regardless of their coverage arrangement. On October 7, 2009, the Departments of Labor, Health and Human Services, and Treasury issued interim final regulations implementing the provisions in Title I of GINA. These regulations became effective as of December 7, 2009, and specifically for plan years beginning on or after December 7, 2009, for group health plans and health insurance issuers.[4]

Title II of GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions—including hiring, firing, job assignments, and promotions—by employers, unions, employment agencies, and labor management training programs. On March 2, 2009, the Equal Employment Opportunity Commission (EEOC) issued proposed regulations for Title II that generally closely track the statutory language.

GINA's Title II Exception for Employer Acquisition of Genetic Information as Part of a Wellness Program

Although GINA broadly prohibits both the acquisition of genetic information, as well as the use of genetic information by employers in employment decisions, it does provide for several exceptions to the prohibition on employer acquisition of this information. Specifically, Title II of GINA allows employers, employment agencies, labor organizations, and training programs to acquire genetic information pursuant to the offering of health or genetic services, including services offered as part of a wellness program.[5] The statute states, in pertinent part, "(i)t shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee except where health or genetic services are offered by the employer, including such services offered as part of a wellness program."[6] The exception provided for by this provision is materially identical for employment agencies, labor organizations, and training programs.

However, employers may collect genetic information as part of a wellness program, pursuant to this exception, *only* if they meet three requirements, as specified in statute. These include

- the employee must provide prior, knowing, voluntary and written authorization;

[4] 74 Fed. Reg. 51633 (October 7, 2009).

[5] P.L. 110-233. Section 202(b)(2), Section 203(b)(2), Section 204(b)(2), and Section 205(b)(2).

[6] P.L. 110-233. Section 202(b)(2)(A).

- only the employee and the licensed health care professional or board-certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and
- any individually identifiable genetic information provided in connection with the health or genetic services provided under this exception is only available for the purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.[7]

The EEOC's Notice of Proposed Rulemaking (NPRM), released on March 2, 2009, elaborates on these requirements. Specifically, it states that written authorization must (1) be written so that the individual from whom the genetic information is being obtained is reasonably likely to understand the form, (2) describe the type of genetic information that will be obtained and the general purposes for which it will be used, and (3) describe the restrictions on disclosure of genetic information.[8]

Importantly, regardless of how an employer may acquire genetic information (through these exceptions), the employer is still absolutely prohibited from using the information to discriminate in employment decisions, such as hiring, firing, and promotion.

Issues for Consideration

A number of issues arise with respect to the interaction between GINA and employer wellness programs. These include issues relating to the use of financial incentives for participation in wellness programs; what an employer may require of an employee in terms of either participation in wellness programs or provision of medical information pursuant to participation in wellness programs; and the relationship between GINA, underwriting, and financial incentives for participating in wellness programs.

Can an Employer Require an Employee to Participate in a Wellness Program Under GINA?

GINA is silent on the issue of whether an employer may require participation in a wellness program (or if a wellness program may be mandatory). However, the Equal Employment Opportunity Commission (EEOC) Notice of Proposed Rulemaking (NPRM) states that "the proposed regulation reiterates the statutory provision [that a covered entity may offer health or genetic services], but further notes that a wellness program seeking medical information must be voluntary, which is a requirement set forth in the ADA."[9] In addition, the regulation refers to "voluntary wellness programs" when discussing allowed exceptions to the prohibition on employer acquisition of genetic information.

This is potentially an important issue with respect to the scope of the protections offered under GINA. If an employer were able to both require participation in a wellness program, and require the provision of certain medical and/or genetic information as part of the wellness program, this would in essence create a requirement that an employee share his or her genetic information with an employer. This would have the impact of limiting the scope of GINA's protections, as it would create an exception to the prohibition on an employer's acquisition of genetic information that

[7] P.L. 110-233. Section 202(b)(2)(B),(C), and (D).

[8] 74 *Federal Register* 9068 (March 2, 2009).

[9] 74 *Federal Register* 9062 (March 2, 2009).

would not be able to be mitigated by either employee choice or behavior. In addition, if both participation and provision of genetic information were able to be required, it would conflict with the statutory requirement under GINA that an employee provide *voluntary* written authorization for health or genetic services. If both were required by the employer, by definition, the employee could not provide voluntary written authorization for health or genetic services.

Can an Employer Require an Employee to Provide Genetic Information as Part of a Wellness Program Under GINA?

As discussed above, an employer may not require that an employee participate in a wellness program (or accept health or genetic services) that requires the provision of medical information. However, an employer may require that, as a condition of participating in a voluntary wellness program, an employee provide certain medical and/or genetic information. This would comply with GINA's protections because if an employee did not want to divulge this information to his employer, he could opt to not participate in the wellness program. Of course, any provision of genetic information on the part of an employee, pursuant to participating in a wellness program, would still have to comply with the three statutory requirements set forth by GINA. The employee would have to provide voluntary, prior, and knowing written authorization; only the employee and the licensed health care professional or board-certified genetic counselor involved in providing the services could have access to individually identifiable information; and any individually identifiable information could not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.

It may appear that a requirement to provide genetic information pursuant to participation in a wellness program conflicts with GINA's requirement that an employee provide voluntary written authorization for health or genetic services. However, the written authorization would still be voluntary in as much as the employee would always have the option of not participating in the wellness program, and thus could voluntarily opt out of providing any genetic information to the employer.

Does GINA Preclude the Use of Financial Incentives to Encourage Participation in Wellness Programs?

Nothing in the statutory language of GINA would preclude the use of financial (or other) incentives by employers for participation in wellness programs. However, the EEOC NPRM notes that the definition of the term "voluntary," specifically with respect to financial incentives for participation in wellness programs, is not a settled matter. Specifically, it states that a wellness program is voluntary "as long as an employer neither requires participation nor penalizes employees who do not participate."[10] This suggests that it is possible that the interpretation may be made that a program could not be defined as voluntary if there are any financial incentives present at all (i.e., if a financial incentive for participation is interpreted as a penalty for not participating). However, it goes on to note that this definition has not been further developed and that comments on this specific point are invited.[11]

[10] 74 *Federal Register* 9062 (March 2, 2009).

[11] HIPAA regulations address the issue of financial incentives and employer wellness programs. For more information about this issue, please see CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones.

Advocates have expressed concern that the scope of GINA may be adversely affected if employers are allowed to offer any financial incentives for participation in wellness programs.[12] For example, the Council for Responsible Genetics maintains that wellness programs may be considered truly voluntary only if any incentives for participation are prohibited and if voluntary wellness programs are prohibited from requiring a health risk assessment.

In addition, it is possible that where an employer wellness program *requires* the provision of certain genetic information (e.g., family history of cancer or heart disease) that the literal effect of this could be to discourage participation by those individuals with certain family histories (i.e., genetic information). This may occur because, although GINA's protections are in place and discrimination based on genetic information is prohibited in employment and health insurance, individuals may not fully trust these protections and may prefer to keep that information private from their employer, rather than accrue the benefits of participation in the wellness program. Although this requirement is facially neutral it may in fact discourage the participation of individuals with certain family histories. Conversely, it is possible that individuals with a certain family history would prefer to take advantage of the services offered through a wellness program, and the potential for prevention, and would be more comfortable that the protections in place under GINA would protect them adequately.

Financial Incentives for Participation in a Wellness Program and Underwriting

Advocates have expressed concern that if an employer, who is also acting as an insurer, collects genetic information through a wellness program, and if these employers then adjust an employee's premium contribution based on participation in a wellness program, this may violate GINA's prohibition on the use of genetic information for purposes of underwriting under Title I of the Act. Specifically, GINA provides that "a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes."[13] For purposes of Title I of the Act, the term "underwriting purposes" is defined as

> with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—''(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage; ''(B) the computation of premium or contribution amounts under the plan or coverage; ''(C) the application of any pre-existing condition exclusion under the plan or coverage; and ''(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.[14]

The interim final regulations issued by the Departments of Labor, Health and Human Services, and Treasury clarify that the definition of "underwriting purposes" should be interpreted broadly to include activities outside the scope of those used for rating and pricing a group policy. Specifically, the regulation explains that the definition includes "changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program."[15] Many HRAs collect family medical history,

[12] Genetic Alliance Webinar, May 15, 2009. "Genetic Information Nondiscrimination Act: Title II (Employment)." Accessed at http://resourcerepository.org/documents/752/ginaimplementation:titleii/#.

[13] P.L. 110-233. Section 101(b).

[14] P.L. 110-233. Section 101(d).

[15] 74 Fed. Reg. 51663 (October 7, 2009).

which falls under the scope of the definition of genetic information under GINA. For this reason, wellness plans administered by health plans or health insurance issuers that collect this information through HRAs, and that provide financial rewards for participation and for completion of the HRA, would be in violation of the statutory prohibition against the request of genetic information for underwriting purposes. Importantly, the violation is considered to be absolute, regardless of the amount of the financial award associated with the wellness program or whether the rewards are based directly on the outcome of the assessment.

There are certain circumstances under which a plan or issuer may either collect genetic information through an HRA *or* provide a financial incentive for participation in a wellness program or for completion of an HRA. In the first case, a plan or issuer may lawfully collect genetic information through an HRA if there is *no reward* to the enrollee associated with completing the HRA. In the second case, a plan or issuer may lawfully provide a financial incentive for participation in a wellness program or for completion of an HRA if the HRA does not collect any genetic information, including family history.

This regulatory determination raises several potentially consequential issues for consideration. First, it will most likely also affect the provision of services or collection of information through disease management programs, administered by a plan or issuer, and which include a financial incentive for participation. Second, it is possible that fewer plans and issuers will opt to offer wellness programs, or disease management programs, due to the increased cost of compliance for the plan and the restrictions on the type of information that may be collected in the context of a financial incentive. Additionally, if financial incentives are not offered, enrollees may be less inclined to participate in these programs. The combination of these two factors might result in a decrease in the early identification of disease, or its appropriate management, and a concomitant increase in morbidity and mortality as well as health care costs (accruing to both the payer and society broadly). And third, this may create a situation whereby certain employers—those who are also acting as health insurance issuers—will have to adhere to these requirements in terms of financial incentives for wellness programs, whereas others—those not acting in such a capacity—might be required to comply with different requirements relating to the provision of financial incentives and wellness programs, based on the EEOC's interpretation of this issue. The EEOC has not yet issued a final rule on Title II so it is not clear if the requirements will differ.

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